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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,941	10/14/2003	Chin-Ming Chang	17501CON1 (AP)	7685

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EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,941	CHANG ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgment is made of applicant's filing of an amendment and Declaration on 03/08/2007.

2. Applicant's arguments and Declaration have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson (Arch Ophthalmol., Vol. 119, 2001, pp. 492-495) in view of Bandyopadhyay et al. (US 2002/0128267 A1).

The amended claims read on a method of treating glaucoma or ocular hypertension comprises topically administering a therapeutically effective amount of a single composition comprising about 0.2% by weight of brimonidine and about 0.5% by weight of timolol in a pharmaceutically acceptable carrier thereof, to the affected eye, wherein said composition is administered twice a day or less often. Further limitation includes "brimonidine is administered only in the composition" (claim 31).

Larsson teaches the topical administration of 0.2% brimonidine with 0.5% timolol, alone and in combination, for the treatment of glaucoma by lowering intraocular pressure (see page 493, column 1, line 24 thru column 2, line 5 under the heading of "Subjects and Methods"), wherein brimonidine and timolol is administered twice a day, for example brimonidine is administered separately 5 minutes apart from the administration of timolol.

Bandyopadhyay is being supplied as a reference to demonstrate the state of art knowledge in formulating pharmaceutical combination of active agents (e.g., brimonidine, timolol, COX-2 inhibitor, etc...) in separate composition or a single composition, including

topical ophthalmic formulation (see, para. [0411], [0507], [0512], [0513], [0514], [0123] and [0127]). Bandyopadhyay also teaches the advantage of delivering drugs in combination including "the reduction of side effects of the individual therapeutic compounds", "greater patient compliance" and/or "maximize the therapeutic effect at higher dose" when compared to the monotherapy (see para. [0510]-[0511]).

The teaching of Larsson differs from the claimed invention in the administration of brimonidine and timolol in a single composition. To incorporate such teaching into the teaching of Larsson, would have been obvious in view of Bandyopadhyay who teaches the state of art knowledge in preparing pharmaceutical combination of active ingredients (including brimonidine and timolol) which are intended for ophthalmic therapeutic application in separate composition or a single composition.

As discussed above, Larsson makes clear that brimonidine and timolol have been used alone or in combination for the treatment of glaucoma by lowering IOP. Furthermore, Bandyopadhyay makes clear that determination of formulating two compositions each of which is taught by prior art to have common utilities in a single composition or separate composition is well within the skill of artisan. Thus, one having ordinary skill in the art would have been motivated to make such modification to increase the efficacy of drugs and extend the usage of said drugs by making brimonidine and timolol in a single composition to accommodate patient's preference and needs where the compliance could be improved by delivering the drugs in single application.

One having ordinary skill in the art would have been motivated at the time of the invention was made to combine these references and make the modification because they are

drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Response to Arguments

4. Applicant's arguments/Declaration filed 03/08/2007 have been fully considered but they are not persuasive.

Applicant's argument in the response/Declaration takes the position that the showing of commercial success provided in the Declaration is sufficient to overcome a prima facie case of obviousness. Applicant alleges that "total quarterly sales of a topical ophthalmic solution containing 0.2% brimonidine by weight and 0.5% timolol by weight steadily and significantly increased, while the sales of brimonidine alone were roughly constant".

This argument is not found persuasive. Unlike the applicant's argument, there is no objective evidences that the alleged commercial success is not "the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention". Applicant's "conclusory statements or opinions that increased sales were due to the merits of the invention are entitled to little weight" to the merits of the claimed invention. Thus, the examiner maintains that there is a reasonable expectation of success in light of Larsson and Bandyopadhyay to arrive at the claimed invention. Lastly, secondary consideration of nonobviousness such commercial success does not overcome the examiner's obviousness finding since the applicant fails to provide the required nexus for nonobviousness based on commercial success.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614